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(54) Infusion device for the subcutaneous administration of an active substance

(57) The invention concerns a catheter head for subcutaneous administration of an active substance, whereby the catheter head includes at least:

a) a cannula housing (2) with a cannula (1) that is to be placed in a tissue, whereby a feed line (18, 19) to the cannula (1) for the active substance is constructed in the cannula housing (2) and the cannula housing (2) comprises an underside (12) that can be placed flush onto the tissue and that is prepared for a fixation to the tissue,
b) a needle holder (3) with a supply (5) for the active substance and a connecting needle (4) that is inserted into the feed line (18, 19) of the cannula housing (2), whereby the needle holder (3) and the cannula housing (2) are detachably attached to each other or are attached, and
c) guide means, which for the positioning and during the insertion of the connecting needle (4) into the feed line (18, 19) of the cannula housing (2) lead the needle holder (3) to the cannula housing (2), whereby
d) the needle holder (3) forms a guiding sleeve (7) that axially surrounds the connecting needle (4), which
e) is narrowly slide-guided over a cylindrical extension (6) of the cannula housing (2) which encloses an inlet (9) and an adjacent area of the feed line (18, 19) of the cannula housing (2) during the insertion of the connecting needle (4).

Description

[0001] The invention concerns a catheter head for the subcutaneous administration of an active substance, in particular a medical active substance such as, for example, insulin. The catheter head comprises a cannula housing with a cannula and a needle holder, that is to be connected to the cannula housing, with a supply for the active substance. The cannula protrudes from the cannula housing and is placed in a tissue. The cannula together with the cannula housing can be constructed as a single piece, in another preferred embodiment it is attached and/or anchored in the cannula housing. It can be designed as a rigid part, for example, as a steel cannula, or flexible, in particular, bendable. A passage channel for the active substance to the cannula is designed in the cannula housing. The cannula housing is shaped in such a way that it is positioned flush on the tissue into which the cannula is placed, and is prepared for a fixation and/or attachment onto the tissue.
[0002] A connecting needle, which is led into the passage channel of the cannula housing for establishing a connection, is rigidly attached to the needle holder. The cannula and the cannula housing both remain at the site of the fixation in and on the tissue whereas the needle holder can be repeatedly connected to, and again separated from, the cannula housing. Preferably, these engage with each other automatically during connection, in particular due to the detachable anchoring of the needle holder to the cannula housing. Guide means, which guide the needle holder at the cannula housing, are provided for the positioning of the connecting needle relative to the passage channel of the cannula housing and for the insertion of the connecting needle in the passage channel.
[0003] A catheter head of the aforementioned kind is known from the US-PS 5,522,803. The guide means of the known catheter head are formed by a pair of guidance pins which protrude from the needle holder on both sides of the connecting needle as well as parallel to it. Accordingly, the cannula housing is provided on both sides of an inlet into the passage channel with guide shafts into which each of the guide pins enters for the insertion of the connecting needle. The connecting needle is positioned relative to an inlet by the cooperation of this guide pin with the guide shaft and is centered during insertion in the passage channel. In the course of the advancement of the connecting needle in the passage channel, the needle holder is anchored by an automatically engaging snap-on connection to the cannula housing.
[0004] It is the objective of the invention to provide a catheter head, for the subcutaneous administration of an active substance, of which the cannula housing and needle holder can be correctly connected to each other in a

simple way and which is easy to manufacture.

[0005] According to the invention, in the case of a catheter head of the kind described in the beginning, the guide means which are constructed on the needle holder are formed by a guide sleeve which axially surrounds the connecting needle and which, when connecting the needle holder and the cannula housing, that is, when inserting the connecting needle, is narrowly slide-guided over a cylindrical extension of the cannula housing. The cylindrical extension surrounds the inlet and a section of the passage channel of the cannula housing that connects to it. The invention ensures a secure insertion of the connecting needle without requiring the construction of additional guide pins. Furthermore, the guide sleeve represents a protection means both for the needle as well as for the user. The guide sleeve can be pierced but it is preferably designed as a closed sleeve part.

[0006] In one preferred embodiment example the cannula housing comprises a compact front section from the underside of which the cannula protrudes and from the rear of which a superimposed disk shaped section extends the underside of the cannula housing that lies on the tissue, and that protrudes from the cylindrical extension. An upper side of the disk-shaped rear section of the cannula housing that faces the cylindrical extension and an underside of the needle holder act as additional guide means when the cannula housing and the needle holder are connected together and prevent a rotation of the needle holder relative to the cannula housing around the longitudinal axis of the connecting needle.

[0007] Preferably, an additional passage is constructed in the cannula housing for a piercing needle for the cannula. This passage points at an angle with respect to the connecting needle when the cannula housing and the needle holder are connected. The passage channel that takes in the connecting needle leads into this additional passage which extends the passage channel up to the cannula after the cannula has been placed and the piercing needle has been retracted. Because a piercing needle does not need to be retracted from the passage channel, into which, after the placing of the cannula and the attachment of the cannula housing, the connecting needle is inserted, a complete precharging of the catheter head up to the cannula, that is priming, is possible when the cannula housing and the needle holder are in the assembled state.

In a further embodiment, however, a flexible cannula extends the passage channel flush. In a third embodiment the cannula is formed by the piercing needle itself.

[0008] In a preferred manufacturing process, the prefabricated cannula is molded into the cannula housing during the injection molding of the cannula

housing. For this the cannula comprises preferably a widening in a rear section which anchors the cannula in the cannula housing during injection. The cannula is preferably made from a soft plastic material, in particular, Teflon. For the cannula housing and also for the needle holder a thermoplastic plastic material can be used.

[0009] In the following preferred embodiment examples of the invention are explained with the help of figures. They show:

Figure 1 a catheter head in the assembled state,
Figure 2 the catheter head according to Figure 1 with the components of the catheter head represented in exploded view,
Figure 3 the catheter head according to Figure 2 immediately before the assembly,
Figure 4 a longitudinal section of the catheter head according to the Figures 1 to 3 in assembled state,
Figure 5 a second embodiment example of a catheter head, and
Figure 6 a longitudinal section of the catheter head according to Figure 5.

[0010] Figure 1 shows a catheter head with a cannula 1 which extends vertically from an underside of the catheter head. The cannula 1, made of a soft plastic material, in the embodiment example, Teflon, closely surrounds a piercing needle N which protrudes through the catheter head perpendicularly relative to its flat underside. The catheter head of Figure 1 forms the front end of a catheter 5, which is indicated in figures 2 to 4. The catheter with the catheter head is placed by the user, for example, a diabetic, himself. Hereby, the piercing needle N and the cannula 1 are inserted perpendicularly under the skin into the tissue, and the underside of the catheter head is positioned adjacent to and/or fixed or attached to the skin. The fixation is achieved by a self-adhesive pad or plaster. Such a pad increases the underside of the catheter head that is available for the adhesion. In the case that the underside as such provides a sufficient size, provision of such an underside already suffices as an adhesive area. After placing the cannula 1, the piercing needle N is retracted from the catheter head, so that only the thin, flexible, in particular bendable, cannula 1 remains in the tissue.

[0011] The catheter head comprises a cannula housing 2, which remains together with the cannula 1 at the piercing point and which comprises in particular also an underside that serves for the fixation of the catheter head, and a needle holder 3 which forms the front end of the catheter 5. The cannula housing 2 and the needle holder 3 combine with each other through a plug-in connection that can be repeatedly connected and disconnected.

[0012] In Figure 2 the cannula housing 2 and the needle holder 3 are separated from each other, they are, however, depicted already aligned with respect to each other for plugging them together. Furthermore, the individual components of the catheter head which are to be manufactured separately are individually depicted removed from their assembled position. All the individual components are aligned relative to each other according to their assembly position.

[0013] The active substance is supplied through the catheter 5 to the needle holder 3. It is passed through a connecting needle 4, contained within the needle holder 3, into a passage channel in the cannula housing 2 and then to the cannula 1 and through the cannula 1 to the desired location into the tissue. In Figures 1 to 4 the piercing needle N depicted has already been removed. An inlet 9 and an adjacent section of the passage channel of the cannula housing 2 are surrounded by a cylindrical extension 6 that protrudes from a rear side of the cannula housing 2. The passage within the catheter head is best seen in detail in the longitudinal section of Figure 4.

[0014] Figure 3 shows the cannula housing 2 and the needle holder 3, each also arranged in a position relative to each other that is suitable for the assembly. From this position, the needle holder 3 is advanced in a straight line in the longitudinal direction of the connecting needle 4, which points to the inlet 9, towards the cannula housing 2 and attached. The supply and attaching direction of the needle holder 3 in essence points parallel to the skin surface. The catheter is therefore led away parallel to the skin surface; however, it can also be led away under an angle with the skin surface.

[0015] In the assembled sate, the catheter head has overall the shape of a semi-ovaloid with a flat underside 12, which towards the edge descends rounded from the skin and which crosses over into a, in certain sections, convex, and, in certain sections, concave, curving upper side. The cannula housing 2, on which the underside 12 that is placed on the skin is formed, comprises a rear disk-shaped section 11 and a front section 10 that is thickened in relation to the same, from the underside 12 of which the cannula 1 and from the rear of which the cylindrical extension 6 and, facing the same, the disk-shaped section 11 protrudes towards the rear into the direction of the needle holder 3, to be advanced towards the same. The upper side 13 of the rear section 11 is curved concavely and adapted to the correspondingly to the outside curved underside 14 of the needle holder 13. The upper side of the front section 10 is on the other hand curved convexly outwards. The needle holder 13 has a symmetrical shape, that is, its upper side and its underside 14 are curved outwards in the same way; furthermore, the needle holder 13 [Tr.- the original has the number 3 here, which I believe is a mistake and must be 13]

is symmetrical in top view in relation to its central axis. Because of the symmetry, the under and upper side of the needle holder 13 can be exchanged when they are plugged together. This simplifies the handling, since the correct alignment can be verified simply by touch alone.

[0016] During interaction with a guide sleeve 7 provided on the needle holder 3, the cylindrical extension 6 acts as a guide means for positioning the connecting needle 4 relative to the inlet 9 and for correct straight guidance of the connecting needle 4 within the section of the passage channel following the inlet 9. Therefore, according to the invention, a part of the cannula housing 2 that surrounds the passage channel, namely the cylindrical extension 6, is formed to protrude from the cannula housing 2 and can thus be used as a guide means for inserting the connecting needle 4. The guide means on the needle holder 3, that interact with the same, is formed by the guide sleeve 7, simultaneously protecting the connecting needle 4, coaxially arranged in the same, against damage; in addition, it protects the user against possible injury due to a projecting needle, for instance, when touching, or in general, due to lack of attention during handling. The guide sleeve 7 protrudes over the connecting needle 4 in its longitudinal direction.

[0017] The guide sleeve 7 is formed by forming two longitudinal slots 17, that is, the sleeve 7 is between these two slots 17 as a sleeve-shaped extension. The guide sleeve 7 could be formed in principle by the needle holder 3 as a whole, that is, being formed as a straight cylindrical recess in an otherwise full needle holder 3, which would then be regarded in total as a guide sleeve.

[0018] However, two elastic snap-on fingers 16 are formed by the slots 17 on both sides of the guide sleeve 7, protruding over the guide sleeve 7. When attaching the needle holder 3, the snap-on fingers 16 engage with appropriate guide shafts 15, provided on both sides of the cylindrical extension 6 in the cannula housing 2. During the insertion or joining of the connecting needle 4, the snap-on fingers 16 slide over guide faces of their guide shafts 15 tapered towards each other and are bent by the same towards each other. The elastically bendable snap-on fingers 16 are snapped out by their engaging tabs behind protrusions formed in the guide shafts 15 upon the connecting needle 4 having been completely inserted, and thus anchoring the needle holder 3 at the cannula housing 2 by gripping behind the appropriate projections of the guide shafts. The snap-on connection is released by pressing the snap-on fingers 16 towards each other in their knurled sections. After having released the grip from behind in this way, the needle holder 3 may be retracted from the cannula housing 2.

[0019] Figure 4 shows in longitudinal section the catheter head in assembled state. The guide sleeve 7 is completely pushed over the cylindrical extension 6,

with its front edge contacting the rear of the cannula housing 2, from which the cylindrical extension 6 protrudes. In this state, the snap-on fingers 16 grip behind the appropriate tabs in the guide shafts 15. Accidental release of the needle holder 3 is therefore not possible.

[0020] When attaching the needle holder 3, the underside 14 of the needle holder 3 slides along the curved upper side 13 of the cannula housing 2. The guide sleeve 7 is positioned flush with the cylindrical extension 6 for positioning the connecting needle 4, whereby the needle holder 3 can be displaced while being supported on the upper side 13 of the cannula housing 2. The cylindrical extension 6 is centered in the guide sleeve 7 when first being pushed over the cylindrical extension 6, because the front edge of the cylindrical extension 6 is slightly rounded. Thereafter, the needle holder 3 is pushed forward over the cylindrical extension 6 with its guide sleeve 7. The connecting needle 4 pierces thereby a septum 8 directly arranged behind the inlet 9 in the passage channel of the cylindrical extension 6. The septum 8 is designed to hermetically seal the passage channel of the cannula housing 2 even after repeatedly being pierced. Directly behind the septum 8, the passage channel is provided with a dome 18 into which the connecting needle 4 protrudes. A straight channel section 19, leading into a cavity 20 in the front section 10 of the cannula housing 2, arranged flush with the connecting needle 4, follows the domed section 18. The cannula 1 also ends in this cavity 20. The piercing needle N protrudes through the cavity at an angle, in this embodiment a right angle, with respect the connecting needle 4 and the channel section 19. The piercing needle N projects through the cannula housing 2 and extends in an angle, in this embodiment example in a right angle, with respect to its underside 12. In this arrangement, the piercing needle N is advantageously not guided through that part of the passage channel of the cannula housing 2 into which the connecting needle is introduced. Due to this arrangement, the piercing needle N does not have to be removed first in order to be able to introduce the connecting needle into the cannula housing. This is advantageous for so-called priming, during which the catheter head H is filled as far as possible completely with the active substance prior to placing the cannula 1. This simplifies the handling considerably.

[0021] The cannula 1 is designed as a thin tube, comprising a flange-type widened section 21 at one end. The flange-type widened section 21 is placed in a disk-shaped recess of the cannula housing 2, thus anchoring the cannula 1.

[0022] Another septum 22, that is inserted opposite the cannula inlet in the cavity 20, seals the cavity 20, which forms part of the passage channel of the

cannula housing 2, after retracting the piercing needle N. The function of the septum 22 is comparable with that of the septum 8. The shape of the cavity 20 is essentially cylindrical, with the flange-type widened section 21 of the cannula 1 and the septum 22 forming the opposite faces of the cylindrical cavity 20 and between which the channel section 19 ends. For priming, the piercing needle N comprises an opening in its section located between the flange-type widened section 21 and the septum 22.

[0023] Figure 4 clearly shows the flush support of the needle holder 3 over the full surface of the upper side 13 of the disk-shaped rear section 11 of the cannula housing 2. In addition, it is shown that a clearance remains between the upper side 13 and the cylindrical extension 6 into which the guide sleeve 7 enters upon the needle holder 3 being plugged on. In principle, the mentioned clearance between the disk-shaped section 11 and the cylindrical extension 6 is not required. The cylindrical extension 6 could, for example, be located flush directly on the disk-shaped section 11. In this design, the underside of the guide sleeve 7 would be suitably open. The internal jacket face, being the actual guide for the guide sleeve 7, and the external jacket face of the cylindrical extension 6, also do not need to be perfectly cylindrical in shape, although this is preferred They could also, for example, be shaped as a cuboid. However, it is essential that sufficient slideway faces are available for positioning and neatly guiding the connecting needle 4. The guidance and, in particular, the securing of the needle holder 3 against rotation relative to the fixed cannula housing 2 is improved by the upper side 13 of the cannula housing 2 and the underside 14 of the needle holder 3 acting as guide faces. The shape of these two guide faces 13 and 14 already ensures correct alignment, in particular centering, during assembly.

[0024] Figures 5 and 6 show a modified embodiment example, in which the piercing needle is pierced through the same passage channel of the cannula housing 2 into which the connecting needle 4 is to be inserted after placing the cannula 1. With the exception of the arrangement of the piercing needle and the cannula 1, the catheter heads of Figures 5 and 6 correspond to the arrangement described in the above; reference is therefore made to that description.

[0025] In embodiment examples according to the invention, the cannula housing 2 may be produced in a single injection molding cycle. For this purpose, the prefabricated cannula 1 including its widened section 21 and possibly also the septum 8 and the septum 22, are inserted into the injection molding tool and directly molded into the same as an integral part of the cannula housing 2. The required attachments in the shape of all-round shoulders surrounding the aforementioned components are specified by the

injection molding tool. The septums 8 and 22 can also be inserted into the cannula housing 2, whereby the cannula housing 2 is remolded in another production cycle for retaining the septums 8 and 22. In particular, the molding of the cannula 1 is a considerable simplification of the process for manufacturing the cannula housing 2.

Patent Claims

1. Catheter head for the subcutaneous administration of an active substance, where the catheter head comprises at least:
a) a cannula housing (2) with a cannula (1) that is to be placed in a tissue, whereby a feed line (18, 19) to the cannula (1) for the active substance is constructed in the cannula housing (2) and the cannula housing (1) comprises an underside (2) that can be positioned flush on the tissue and that is prepared for a fixation to the tissue,
b) a needle holder (3) with a supply (5) for the active substance and a connecting needle (4) that is inserted in the feed line (18,19) of the cannula housing (2), whereby the needle holder (3) and the cannula housing (2) after insertion of the connection needle (4) are detachably attached to each other or are attached, and
c) guide means, which for the positioning and during the insertion of the connecting needle (4) in the feed line (18, 19) of the cannula housing (2) lead the needle holder (3) to the cannula housing (2),

characterized by that

d) the needle holder (3) forms a guiding sleeve (7) that axially surrounds the connecting needle (4), which
e) during the insertion of the connecting needle (4) is narrowly slide-guided over a cylindrical extension (6) of the cannula housing (2) which encloses an inlet (9) and an adjacent area of the feed line (18, 19) of the cannula housing (2).

2. Catheter head according to claim 1, characterized by that the guide sleeve (7) comprises a jacket face that surrounds the connecting needle (4).

3. Catheter head according to claim 1 or 2, characterized by that the cannula housing (2) comprises a disk-shaped rear section (11) and a thicker front section comprising the passage channel (18, 19), in which or onto which the cannula (1) is attached, and from which the cylindrical extension (6) protrudes

over the disk-shaped rear section (11).

4. Catheter head according to the preceding claim, characterized by that a clearance for sliding over of the guide sleeve (7) remains between the cylindrical extension (6) and an upper side (13) of the disk-shaped rear section (11).

5. Catheter head according to at least one of the preceding claims, characterized by that, during insertion of the connecting needle (4), an upper side (13) of the cannula housing (2) forms a support and an additional slide way for said needle holder (3).

6. Catheter head according to the preceding claim, characterized by that the upper side (13) is adapted to an underside (14) of the needle holder (3) which is curved in cross direction to the connecting needle and thus forms the additional slideway, the additional slideway preferably extending parallel to the cylindrical extension (6).

7. Catheter head according to at least one of the preceding claims, characterized by that an underside (14) of the needle holder (3) is during the positioning and insertion of the connecting needle (4) flush positioned on an upper side (13) of a rear section (11) of the cannula housing (2).

8. Catheter head according to at least one of the preceding claims, characterized by that the needle holder (4) comprises an upper side symmetrical to its underside (14), whereby the underside (14) and the upper side are preferably curving outwardly away from each other.

9. Catheter head according to at least one of the preceding claims, characterized by that a piercing needle (N) for the cannula (1) protrudes through the cannula housing (3) at an angle with respect to the longitudinal direction of the inserted connecting needle (4), whereby the passage channel (18, 19) for the connecting needle (4) leads at an angle into an additional passage (20) for the piercing needle (N).

10. Catheter head according to at least one of the preceding claims, characterized by that the prefabricated cannula (1) is injection molded in the cannula housing (2) during the injection molding of the cannula housing (2).

European Patent Office

EUROPEAN SEARCH REPORT

Number of the application EP 99 81 0409

RELEVANT DOCUMENTS			
Category	Characterization of the document with indication, as far as required, of the relevant parts	Concerns claim	Classification of the application (Int.Cl.6)
A,D	US 5 522 803 A (TEISSEN-SIMONY) June 4, 1996 (06-04-1996) * Summary; Figures 3, 5-15 *	1-10	A61M25/00 A61M25/06 A61M39/02
A	EP 0 792 658 A (BECTON DICKINSON CO.) September 3, 1997 (09-03-1997) * Summary; Figures 1, 2, 4-6 *	1-10	
			investigated subject areas (Int.Cli.6)
			A61M
The present Search Report is established for all patent claims			
Research location	Completion date of the investigation	Examiner	
THE HAGUE	August 19, 1999	Michels, N	

CATEGORY OF THE MENTIONED DOCUMENTS

X : of special meaning examined alone
Y : of special meaning in connection with another disclosure of the same category
A : technological background
O : non-written disclosure
P : intermediate documents

T : the theories or principle that underlies the invention
E : former patent document, that, however, was disclosed first or after the application date
D : the document that is cited in the application
L : documents cited for other reasons
& : document that corresponds to a member of the patent family

APPENDIX OF THE EUROPEAN SEARCH REPORT CONCERNING THE EUROPEAN PATENT APPLICATION No. EP 99 81 0409.

In this appendix the members of the patent families of the in the above mentioned European Search Report cited patent documents are indicated. The specifications concerning the family members correspond to the status of the file of the European Patent Office.
These specifications serve only for informing and are subject to change

08-19-1999

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For further details concerning the appendix: see the Official Journal of the European Patent Office No. 12/82